1. The information disclosure statement (IDS) submitted on February 22, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner based of the search report filed in this National Stage application.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cui. In the paper Cui teaches an optical fiber pH sensor based on an immobilized indicator. An optical fiber pH sensor which has the immobilized pH sensitive indicator dye reagents on the tip of the optical fiber was studied. The probe is made by covalently immobilizing the phenol red, bromine phenol blue or bromothymol blue on the polyacrylamide microsphere fixed by porous polytetrafluoroethylene (PTFE) film. A gap between the dye and optical fiber was used to make the diffusion of the hydrogen ion more easily. The parameters of the optical fiber pH sensor are given. The ranges of measurement are 3.0-5 pH 7.0-8.5 pH, 8.0-10.0 pH for bromine phenol blue, phenol red and bromothymol blue, respectively. The sensitivity is 66.6 mV/pH. The probe has the precision better than 0.05 pH. The linear correlation coefficient is 0.999. The response time is 1-2 min. The hysteresis is 0.52%. The repeatability is 0.013 mV while the stability is 0.015 pH/hour. Figure 2 shows the system including a reflection mirror. The description of figure 2 on page 388 (section 3.1) teaches a fiber bundle having both input and output fibers.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cui as applied to claim 1 above, and further in view of Berlin (DD 296757). Cui does not teach that the reagent can be replaced or exchanged.

In the published application Berlin teaches a reusable fiber-optic sensor. Fiber-optic (bio)sensors are described which contain a reagent phase separable from and optically coupled to the fiber optics, so that the reagent phase can be exchanged or replaced in a reproducible position relative to the fiber optics. The reagent phase contains immobilized biological components and/or an indicator system, and its optical properties (absorbance, fluorescence, luminescence) change on exposure to the analyte. This arrangement reduces the cost of sensors which utilize irreversible reactions, unstable biological components, etc., as the reagent phase may comprise a disposable component of the sensor. Thus, a crosslinked sulfated polystyrene bead 0.8 mm in diameter was shaken successively in solutions containing N,N-diethyl-p-phenylenediamine-HCl (I; H_2O_2 indicator) and glucose oxidase, and washed. The bead was placed in a fiber-optic cuvette in which it acted as a lens which, together with a concave mirror, focused light emitted by the optic fiber back onto the tip of the fiber. On addition of a glucose solution to the cuvette, the change in absorbance of the bead due to I oxidation by H_2O_2 formed in the glucose oxidase reaction was registered. Various configurations of the reagent phase are illustrated schematically in the figures. The device is for medical diagnosis, analysis of environment or foodstuffs, or chemical or biochemical process control.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Cui reagent in replaceable or exchangeable form as Taught by Berlin because of the cost advantages taught by Berlin.

6. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cui and Berlin as applied to claims 1-2 above, and further in view of Park or Bae (US 6,103,865). Cui does not teach that the claimed pH sensitive monomers or the claimed sulfonamides.

In the paper Park teaches novel pH-sensitive polymers containing sulfonamide groups. Novel pH-sensitive polymers were synthesized by copolymerizing a monomer derivatized from

4-amino-N-[4,6-dimethyl-2-pyrimidinyl]benzene sulfonamide (sulfamethazine) with N,N-dimethylacrylamide (see figure 1). The linear copolymers showed pH-sensitive solubility, while chemical crosslinked hydrogels exhibit a relatively sharp transition in swelling around physiological pH. These changes were found to be reversible. By varying the type of sulfonamide and the copolymer composition, a new class of pH-sensitive polymers with a broad range of transition pH can be synthesized. Figure 3 shows the rapid change in transmittance at the point of change.

In the patent Bae teaches a pH-sensitive polymer containing sulfonamide and its synthesis method. There are disclosed pH-sensitive polymers containing sulfonamide groups, which can be changed in physical properties, such as swellability and solubility, depending on pH and which can be applied for a drug-delivery system, bio-material, sensor, etc, and a preparation method therefor. The pH-sensitive polymers are prepared by introduction of sulfonamide groups, various in pKa, to hydrophilic groups of polymers either through coupling to the hydrophilic groups, such as acrylamide, N,N-dimethylacrylamide, acrylic acid, N-isopropylacrylamide, etc, of polymers or copolymerization with other polymerizable monomers. These pH-sensitive polymers may have a structure of linear polymer, grafted copolymer, hydrogel or interpenetrating network polymer. Table 1 teaches the various sulfonamides and their respective pKa. The sulfonamides include most of those claimed in claim 4.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the pH sensitive polymers of Park or Bae into the device of Cui because of their ability to sense change over a narrow pH range as taught by Park and their usefulness in sensors as taught by Bae.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to various fiber optic sensors and pH sensitive materials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571)272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arlen Soderquist/
Primary Examiner, Art Unit 1797